REMARKS

Claims 1 to 3 and 11 to 16 as amended are present for purposes of prosecution.

Reconsideration of the rejection of this application is respectfully requested in view of the above amendments and the following remarks.

Claim 1 has been amended to define the composition as containing 2 to 3% moisture and to define the metformin as being compressible. In addition, Claim 1 has been amended to define the formulation as being devoid of an enteric coating. Bases for these amendments are found in the specification at pages 7, lines 19 to 24, page 17, lines 13 to 15, and page 25, lines 16 to 18.

Applicants' invention as claimed in Claim 1 is directed to a pharmaceutical composition which is in a single dosage formulation of metformin and glipizide which includes 2 to 3% by weight moisture. The formulation has a controlled moisture content of 3% or less by weight so that the glipizide does not hydrolyze and the metformin includes sufficient moisture to allow it to be compressed when forming a tablet.

Applicants' invention as defined in Claim 2 is directed to a single dosage formulation which is a tablet.

In Claim 3, Applicants' tablet of Claim 2 includes an outer protective coating or finishing layer surrounding the tablet.

It should be pointed out that Applicants' formulation includes an amount of moisture (2 to 3% by weight) which is below that which would cause the glipizide to hydrolyze, but sufficient to ensure that the metformin is compressible.

In addition, Applicants' formulations do not include any semi-permeable membrane or other type enteric coating. Thus, Applicants formulation is an immediate release formulation since it does not include an enteric coating.

It is submitted that Applicants' composition as now claimed is patentable over U.S. Patent No. 6,099,862 to Chen et al, the only reference cited.

Claims 1 to 3, 11 to 12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (U.S. 6,099,862).

> The Examiner contends that, "Chen discloses a controlled release pharmaceutical tablet containing 500 mg of metformin and 5 mg of glipizide, wherein in core of said composition is prepared by mixing metformin and glipizide with povidone, sodium lauryl sulfate and magnesium stearate and then tablet is seal coated with an opadry materials (Example 2)."

It is submitted that Applicants' invention as claimed is patentable over Chen et al.

Chen et al. disclose a controlled release tablet which as disclosed in Example 2, may include a combination of metformin HCL (500 mg) and glipizide (5 mg) in a tablet core, a seal coat

and a sustained release coating formed of a semi-permeable membrane which is formed of cellulose acetate, triacetin (plasticizer) and PEG400. The sustained release coating includes one hole drilled onto each side of the sustained release tablet, which holes allow for release of drugs.

The tablet cores of Example 2 of Chen et al. are formed by a granulation technique where granules containing metformin and glipizide "are dried in the fluidized bed coater until the loss on drying is less than 2%."

After the seal coating and sustained release semi-permeable membrane coating are applied, the coated tablets are dried before the holes are drilled into the sustained release tablets.

If it is submitted that Applicants' composition as claimed in Claims 1-3, 11-12 and 16 are patentable over Chen et al. As indicated in amended Claim 1, Applicants' tablets are devoid of an enteric coating and therefore are immediate release tablets. The Chen et al. tablets contain a semi-permeable membrane and thus are sustained release tablets, which as shown in Example 2 release drugs over a 16 hour period.

In addition, Applicants' tablets must include sufficient moisture to leave the metformin sufficiently compressible so that tablets may be formed. However, the water content must be 3% or less to ensure that the glipizide will not be hydrolyzed.

There is no disclosure or suggestion in Chen et al. of an immediate release composition or tablet as claimed herein.

There is no disclosure or suggestion in Chen et al. of an immediate release composition or tablet that contains 2 to 3% moisture.

There is nothing in Chen et al. which would motivate one skilled in the art to change the Chen et al. tablet to go from a sustained release tablet with a semi-permeable membrane which includes openings in the tablet to allow drugs to be released to an immediate release tablet which is devoid of an enteric coating.

The differences between Applicants' invention as claimed and the tablet of Chen et al. are significant and unobvious so that the subject matter of Applicants' invention as a whole would not be obvious to one skilled in the art.

In view of the foregoing, it is submitted that Applicants' invention as claimed in Claims 1-3, 11-12 and 16 is patentable over Chen et al.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (U.S. 6,099,862).

The Examiner contends that "the teaching of Chen has been discussed in above 35 U.S.C. 102(b) rejection. The teaching of Chen differs from the claimed invention in the specific dosage amounts of metformin and glipizide in said composition. However, those of ordinary skill in the art will readily optimize effective dosages as determined by good medical practice and the clinical condition of the individual patient. Regardless of the manner of administration, the specific dose may be calculated according to body weight, body surface area or organ size. Further refinement

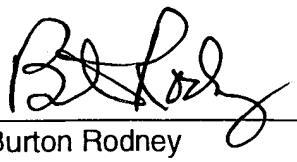
of the calculations necessary to determine the appropriate dosage for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information in column 5, lines 1-15."

Claims 13 to 15 depend from Claim 2 and define compositions containing specific amounts of metformin and specific amounts of glipizide.

It is submitted that the arguments set out above with respect to Chen et al. concerning the rejection of Claims 1 and 3, 11, 12 and 16 apply here as well.

In view of the foregoing, it is submitted that Claims 1 to 3 and 11 to 16 are patentable over Chen et al. and are in condition for allowance.

Respectfully submitted,



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